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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Achim Quaiser

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PILLSBURY WINTHROP SHAW PITTMAN LLP
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER

STEELE, AMBER D

ART UNIT

PAPER NUMBER

1639

MAIL DATE

DELIVERY MODE

05/06/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/525,708	Applicant(s) QUAISER ET AL.	
	Examiner Amber D. Steele	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-76 is/are pending in the application.
- 4a) Of the above claim(s) 48-53 and 60-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-47 and 54-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/18/05; 7/6/05; 5/31/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. The preliminary amendment received on February 18, 2005 canceled claims 1-39 and added new claims 40-76.

Claims 40-76 are currently pending.

Claims 40-47 and 54-59 are currently under consideration.

Election/Restrictions

2. Applicant's election with traverse of Group I (claims 40-59) in the reply filed on March 12, 2008 is acknowledged. The traversal is on the ground(s) that the Patent Office failed to point out why restriction is proper according to MPEP § 806.05(e). This is not found persuasive because the present application is a national stage (371) application and thus falls under the Lack of Unity requirements found in MPEP § 823, § 1850, § 1875, and § 1893. Since the Lack of Unity of the inventions is not traversed, the traversal is moot.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 60-76 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on March 12, 2008.

4. Applicant's election of PVP as the first layer/phase, PVP as the second layer/phase, and the first layer arranged above the second layer as the species of arrangement in the reply filed on

Art Unit: 1639

March 12, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). However, upon further consideration, the species of first layer and second layer is withdrawn. The species requirement for the arrangement is maintained.

5. Claims 48-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on March 12, 2008.

Priority

6. The present application claims status as a 371 (national stage) of PCT/EP03/09223 filed August 20, 2003. In addition, the present application claims foreign priority to EP 02018210.1 filed August 20, 2002.

7. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

8. The information disclosure statement (IDS) submitted on February 18, 2005; July 6, 2005; and May 31, 2007 are being considered by the examiner. Please note: several duplicate citations were found and the duplicates were crossed out; if a translation was not present, only the abstract was considered; and if the references listed on a search report were not listed separately on the IDS and copies were not supplied, the references were not considered.

Specification

9. The disclosure is objected to because of the following informalities: various citations are incomplete (e.g. loc. cit.) in the specification. Completion of the citations (e.g. journal, volume, page numbers, etc.) is suggested. See page 4 for example.

Appropriate correction is required.

10. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Invention as Claimed

11. A device for the isolation and/or purification of nucleic acid molecules comprising at least two layers: a first layer being adapted to bind and/or inactivate inhibitors of the activity or reagents or enzymes used in nucleic acid manipulation and a second layer being adapted to separate a plurality of nucleic acid molecules with respect to their size and wherein said first layer is a first phase of a gel and said second layer is a second phase of said gel and variations thereof.

Please note: the specification, page 35, last paragraph states that approximately 1/4, 1/3, or up to 80-95% of the gel can be one layer.

Please refer to MPEP § 2114 regarding apparatus claims, MPEP § 2115 regarding materials worked upon by the apparatus, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function (*In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997)), recitation with respect to the manner in

Art Unit: 1639

which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus, expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim (*Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969)), and inclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims (*In re Young*, 75 F.2d 996, 25 USPQ 69 (CCPA 1935) and as restated in *In re Otto*, 312 F.2d 937, 136 USPQ 458, 459 (CCPA 1963)).

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 40-46 and 54-59 are rejected under 35 U.S.C. 102(b) as being anticipated by Coffman WO 99/00168 published January 7, 1999 (provided by applicants in the IDS).

For present claims 40-46 and 54-59, Coffman teach a two phase column comprising a top layer of adsorptive media and a second layer of size exclusion media wherein various adsorptive media can be utilized including commercially available reagents comprising agarose and the first adsorptive layer is utilized to extract various components of the sample including proteins (i.e. second layer substantially free of proteins, etc.; please refer to the entire specification particularly the abstract; pages 2-10; Figures 1-2). Please refer to MPEP § 2114 and 2115.

Therefore, the presently claimed invention is anticipated by the teachings of Coffman.

Art Unit: 1639

15. Claims 40-47 and 54-59 are rejected under 35 U.S.C. 102(b) as anticipated by Young et al. Applied and Environmental Microbiology 59(6): 1972-1974, 1993 (provided by applicants in the IDS).

For present claims 40-47 and 54-59, Young et al. teach agarose gel electrophoresis to provide rapid and simple purification of DNA from soil comprising a PVP-LMP agarose gel wherein the second phase of the gel is substantially free of PVPP, CTAB, EDTA, EGTA, cyclodextrins, proteins, polypeptides, antibodies, aptamers, lectins, or ion-exchangers; electricity is utilized to flow a sample through the gel; the gel has a sample loading means provided in a defined array of columns (i.e. where comb has been removed forming wells in gel which form columns after the sample has been run through the gel); DNA; and soil (please refer to the entire reference particularly the abstract; Figure 1; page 1972). Please refer to MPEP § 2114 and § 2115.

Therefore, the presently claimed invention is anticipated by the teachings of Young et al.

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1639

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amber D. Steele/
Patent Examiner, Art Unit 1639

May 1, 2008